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NEWS RELEASE

Johnson & Johnson investigational co-antibody therapy JNJ-4804 shows potential to raise the bar for clinical efficacy in treating refractory inflammatory bowel disease

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JNJ-4804 demonstrated highest rates of clinical and endoscopic outcomes compared to golimumab and guselkumab in patients with ulcerative colitis or Crohn's disease who have had inadequate response to two or more systemic therapy classes

JNJ-4804 is the first and only fixed dose co-antibody designed to deliver molecular synergy in IBD by blocking the complementary IL-23 and TNF pathways

Data from Phase 2b DUET studies show potential to address a critical unmet need and support advancement to Phase 3 trials

CHICAGO, May 5, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced Phase 2b data from two studies evaluating JNJ-4804, an investigational co-antibody therapy targeting both interleukin-23 (IL-23) and tumor necrosis factor-alpha (TNF-α), in patients with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) that is refractory to systemic therapies.[1,2] The late-breaking presentations from the DUET-UC and DUET-CD studies were among the 32 company-sponsored abstracts being presented at Digestive Disease Week (DDW) 2026.

In both studies at Week 48, JNJ-4804 showed meaningful improvements across multiple clinical and endoscopic measures for a subpopulation of patients who are considered highly refractory and have had inadequate response to two or more systemic therapy classes.

DUET-CD study

In the overall population, JNJ-4804[a] demonstrated higher clinical remission[b] rates (50.8%) and endoscopic response[c] rates (38.1%) versus golimumab (25.4% for clinical remission, 19.8% for endoscopic response) at Week 48. The JNJ-4804 rates were also numerically higher than the rates achieved with guselkumab (42.5% for clinical remission and 33.9% for endoscopic response).

In the highly refractory subpopulation of patients with CD who have had inadequate response to two or more systemic therapy classes, JNJ-4804 showed clinically meaningful improvements at Week 48 across multiple clinical and endoscopic endpoints compared to golimumab and guselkumab monotherapies, and placebo. Clinical remission rates for JNJ-4804 were nearly double the highest comparator and more than 60% higher in endoscopic response rate.

"Despite many treatment advances for Crohn's disease over the past two decades, many patients do not achieve long-term disease control with the currently available options, even after trying multiple monotherapies with different classes," said Bruce E. Sands, MD, MS, Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine, and Chief, Division of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System and presenting author of the DUET-CD study. "The results from DUET-CD are particularly promising because they show meaningful clinical and endoscopic improvements in patients who have exhausted existing options."

DUET-UC study

In the overall population, JNJ-4804[a] demonstrated superior clinical remission[d] rates compared to golimumab, with 41.0% of JNJ-4804-treated patients achieving clinical remission at Week 48 versus golimumab (11.5%), and numerically higher rates than guselkumab (34.0%).

In the highly refractory subpopulation of patients with UC who have had inadequate response to two or more systemic therapy classes, JNJ-4804 showed clinically meaningful improvements at Week 48 across multiple clinical and endoscopic endpoints compared to golimumab and guselkumab monotherapies, and placebo, with the clinical remission rate for JNJ-4804 being almost 60% higher than the closest comparator.

"There is a major unmet need for patients who either don't respond or are no longer responding to current UC treatments," said Dr. Maria Abreu, Executive Director of the F. Widjaja Inflammatory Bowel Disease Institute at Cedars-Sinai in Los Angeles and presenting author of DUET-UC. "The ongoing symptoms patients face when their UC is uncontrolled can profoundly impact their lives. The improvements we saw in DUET-UC are very encouraging, offering a potential new approach for patients with few options for long-term disease control."

In both studies, safety findings were generally consistent with the known profiles of the component monotherapies.

Addressing an unmet need in refractory inflammatory bowel disease (IBD)

Inflammatory bowel disease, including UC and CD, affects millions of people worldwide. While advances in biologics and targeted therapies have improved outcomes for many patients, many individuals either no longer respond or lose response over time.[3] It is common for patients to cycle through multiple therapies while experiencing diminishing efficacy, leading to persistent symptoms such as abdominal pain, urgency, and bleeding. Ongoing inflammation can lead to irreversible bowel damage, hospitalization, and surgeries.[4] These challenges highlight a critical need for new treatments that can deliver meaningful disease control for patients who have been refractory to treatment with monotherapies.

"Inflammatory bowel disease involves multiple inflammatory pathways, which may help explain why some patients don't respond or lose response to existing monotherapies," said Esi Lamousé Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson. "By targeting the orthogonal pathways of IL-23 and TNFα, JNJ-4804 yields a synergistic therapeutic approach. The results from the DUET studies highlight its potential to change the treatment landscape."

Based on results from the Phase 2b DUET studies, Johnson & Johnson will be initiating the Phase 3 DUET ENCORE-CD trial in adults with moderately to severely active CD as well as the Phase 3 DUET ENCORE-UC trial in adults with moderately to severely active UC.

With these data, in addition to results from the Phase 3 FUZION study of TREMFYA® (guselkumab) in perianal fistulizing Crohn's disease, Johnson & Johnson therapies account for three late-breaking abstracts featured at DDW.[5]

(Dr. Bruce E. Sands and Dr. Maria Abreau are paid consultants for Johnson & Johnson. They have not been compensated for any media work).

For a full list of all Johnson & Johnson data being presented at DDW visit: **https://www.jnj.com/innovativemedicine/immunology/gastroenterology**.

Editor's Notes:

a. Data represents the JNJ-4804 high dose group.
b. Clinical remission was defined as a CDAI score of <150.
c. Endoscopic response was defined as a >50% improvement from baseline in SES-CD or an SES-CD ≤2, as assessed by central endoscopy reading.
d. Clinical remission was defined as a stool frequency subscore of 0 or 1, a rectal bleeding subscore of 0, and

an endoscopy subscore of 0 or 1 per central review of the video endoscopy.

About the DUET-UC and DUET-CD studies

The DUET-UC (ulcerative colitis) and DUET-CD (Crohn's disease) studies are randomized, double-blind, dose-ranging Phase 2b studies comparing JNJ-4804 with placebo and active comparators, including guselkumab and golimumab. Patients enrolled in both studies had moderately to severely active disease with inadequate response or intolerance to one or more systemic therapy classes, including biologics and targeted oral therapies. Approximately half of participants in each study had previously experienced inadequate response to two or more therapy classes, representing a highly treatment-experienced population. The Phase 2b DUET clinical program builds on earlier proof-of-concept findings from the Phase 2a VEGA study and is intended to inform potential registrational trials.[6,7,8]

The primary endpoint of DUET-UC was clinical remission at Week 48. Key secondary endpoints included corticosteroid-free clinical remission, endoscopic improvement, histologic remission and endoscopic improvement (HREI) at Week 48.[1]

The co-primary endpoints of DUET-CD were clinical remission at Week 48 and endoscopic response at Week 48. Key endpoints included endoscopic remission, deep remission and corticosteroid-free clinical remission at Week 48.[2]

About JNJ-4804

JNJ-4804 is an investigational co-antibody therapy designed to target both interleukin-23 (IL-23) and tumor necrosis factor-alpha (TNF-α), two inflammatory pathways involved in chronic immune-mediated diseases. JNJ-4804 is a fixed-dose combination of two proven therapies, guselkumab and golimumab, in a single, subcutaneous (SC) injection. JNJ-4804 is being studied in the Phase 2b DUET clinical program in inflammatory bowel disease and the Phase 2a AFFINITY study in active psoriatic arthritis (PsA).

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of the immune system's overactive response. Symptoms vary but may typically include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss, and fatigue. Currently there is no cure available for UC.[9]

About Crohn's Disease

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans and an estimated four million people across Europe.[10,11] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other

environmental factors.[12] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Currently no cure is available for Crohn's disease.[13]

ABOUT TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA is the first fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cells that produce IL-23). Findings for the dual-acting mechanism are limited to in vitro studies that demonstrate guselkumab binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.

TREMFYA is a prescription medicine approved in the U.S. to treat:

- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.

TREMFYA is approved in Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis, adults with active psoriatic arthritis, adults with moderate-to-severe Crohn's disease and adults with moderate-to-severe ulcerative colitis.

The legal manufacturer for TREMFYA is Janssen Biotech, Inc.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA. For more information, visit: **www.tremfya.com**.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA?

TREMFYA is a prescription medicine that may cause serious side effects, including:

- Serious Allergic Reactions. Stop using TREMFYA and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

o fainting, dizziness, feeling lightheaded (low blood pressure)
o swelling of your face, eyelids, lips, mouth, tongue or throat
o trouble breathing or throat tightness
o chest tightness
o skin rash, hives
o itching

- Infections. TREMFYA may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA and may treat you for TB before you begin treatment with TREMFYA if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

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o fever, sweats, or chills
o muscle aches
o weight loss
o cough
o warm, red, or painful skin or sores on your body different from your psoriasis
o diarrhea or stomach pain
o shortness of breath
o blood in your phlegm (mucus)
o burning when you urinate or urinating more often than normal

- Liver problems. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA. Your healthcare provider may stop treatment with TREMFYA if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:

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o unexplained rash
o vomiting
o tiredness (fatigue)
o yellowing of the skin or the whites of your eyes
o nausea
o stomach pain (abdominal)
o loss of appetite
o dark urine

Do not use TREMFYA if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA.

Before using TREMFYA, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about TREMFYA?"
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA.
- are pregnant or plan to become pregnant. It is not known if TREMFYA can harm your unborn baby. Pregnancy Registry: If you become pregnant during treatment with TREMFYA, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA. You can enroll by visiting **www.mothertobaby.org/ongoing-study/tremfya-guselkumab**, by calling **1-877-311-8972**, or emailing **MotherToBaby@health.ucsd.edu**. The purpose of this registry is to collect information about the safety of TREMFYA during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TREMFYA?

TREMFYA may cause serious side effects. See "What is the most important information I should know about TREMFYA?"

The most common side effects of TREMFYA include: respiratory tract infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, stomach pain, and bronchitis.

These are not all the possible side effects of TREMFYA. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

Please read the full **Prescribing Information**, including **Medication Guide**, for TREMFYA and discuss any questions that you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

Dosage Forms and Strengths: TREMFYA is available as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

ABOUT JOHNSON & JOHNSON

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to JNJ-4804 and TREMFYA®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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